41.2(68) *Training for imaging and localization studies.* Except as provided in 41.2(76), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 41.2(33) to be a physician who:

a. Is certified in:

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(5) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Radiopharmaceutical chemistry; and
5. Radiation biology.

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
3. Calculating and safely preparing patient or human research subject dosages;
4. Using administrative controls to prevent the misadministration of radioactive material;
5. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
6. Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(3) To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Examining patients or human research subjects and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;
2. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
3. Administering dosages to patients or human research subjects and using syringe radiation shields;
4. Collaborating with the authorized user in the interpretation of radionuclide test results; and
5. Patient or human research subject follow-up; or

c. Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 41.2(68)*"b"*;

d. Be identified on a current Agreement State or NRC license as an authorized user for those uses listed in 41.2(33).

41.2(69) *Training for therapeutic use of radiopharmaceuticals.* The licensee shall require the authorized user of a radiopharmaceutical listed in 41.2(37) for therapy to be a physician who:

a. Is certified by:

(1) The American Board of Nuclear Medicine; or

(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; or

(3) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(4) The American Osteopathic Board of Radiology after 1984; or

b. Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

(1) To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;
2. Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;
3. Use of iodine-131 for treatment of thyroid carcinoma in three individuals;
4. Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals;
5. Use of strontium-89 or samarium-153 for relief of pain in metastatic disease in three individuals; and
6. Use of iodine-131 radiolabeled monoclonal antibody for treatment of non-Hodgkin's lymphoma in three patients; or

c. Be identified on a current Agreement State or NRC license as an authorized user for these uses in 41.2(37).

41.2(70) *Training for therapeutic use of brachytherapy sources.* The licensee shall require the authorized user using a brachytherapy source specified in 41.2(43) for therapy to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology.

(2) To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

1. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
2. Checking survey meters for proper operation;
3. Preparing, implanting, and removing sealed sources;
4. Using administrative controls to prevent the misadministration of radioactive material; and
5. Using emergency procedures to control radioactive material.

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
2. Selecting the proper brachytherapy sources, dose, and method of administration;
3. Calculating the dose; and
4. Postadministration follow-up and review of case histories in collaboration with the authorized user; or

c. Be identified on a current Agreement State or NRC license as an authorized user for the uses in 41.2(43).

41.2(71) *Training for ophthalmic use of strontium-90.* The licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is certified in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

b. Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity; and
4. Radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

1. Examination of each individual to be treated;
2. Calculation of the dose to be administered;
3. Administration of the dose; and
4. Follow-up and review of each individual’s case history; or

c. Be identified on a current Agreement State or NRC license as an authorized user for the use in 41.2(43)*"h."*

41.2(72) *Training for use of sealed sources for diagnosis.* The licensee shall require the authorized user using a sealed source in a device specified in 41.2(41) to be a physician, dentist, or podiatrist who:

a. Is certified in:

(1) Radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device.

(1) To satisfy the requirements for instruction, the training shall include:

1. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

2. Radiation biology; and

3. Radiation protection and training in the use of the device for the purposes authorized by the license.

(2) Reserved; or

c. Be identified on a current Agreement State or NRC license as an authorized user for those uses in 41.2(41).

41.2(73) *Training for teletherapy.* The licensee shall require the authorized user of a sealed source specified in 41.2(49) in a teletherapy unit to be a physician who:

a. Is certified in:

(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology.

(2) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

1. Review of the full calibration measurements and periodic spot checks;

2. Preparing treatment plans and calculating treatment times;

3. Using administrative controls to prevent misadministrations;

4. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

5. Checking and using survey meters.

(3) To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

1. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment and any limitations or contraindications;
2. Selecting the proper dose and how it is to be administered;
3. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and
4. Postadministration follow-up and review of case histories;

c. Be identified on a current Agreement State or NRC license as an authorized user for teletherapy.

41.2(74) *Training for teletherapy physicist.* The licensee shall require the teletherapy physicist to:

a. Be certified by:

(1) The American Board of Radiology in:

1. Therapeutic radiological physics;
2. Roentgen-ray and gamma-ray physics;
3. X-ray and radium physics; or
4. Radiological physics; or
5. The American Board of Medical Physics in radiation oncology physics; or

(2) Reserved; or

b. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full-time training in therapeutic radiological physics and also one year of full-time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in 41.2(21), 41.2(58), 41.2(59), and 41.2(60) under the supervision of a teletherapy physicist during the year of work experience.

c. Be identified on a current Agreement State or NRC license as a teletherapy physicist.

41.2(75) *Training for experienced authorized users and teletherapy or medical physicists.*

a. An individual identified as a teletherapy or medical physicist on an NRC or agreement state license or a permit issued by an NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before January 1, 2003, does not need to comply with the training requirements of 41.2(73).

b. Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material issued by this agency, the NRC, or agreement state, a permit issued by an NRC master material licensee, a permit issued by an NRC broad scope permittee before January 1, 2003, who perform only those medical uses for which they were authorized before that date need not comply with the training requirements of 41.2(68), 41.2(69), 41.2(70), 41.2(71), 41.2(72), or 41.2(73).

41.2(76) *Physician training in a three-month program.* A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program, is exempted from the requirements of 41.2(67) or 41.2(68).

41.2(77) *Recentness of training.* The training and experience specified in 41.2(65) to 41.2(79) and 41.2(81) shall have been obtained within the seven years preceding the date of application or the individual shall have had related continuing education and continuing applicable experience since the required training and experience were completed.

41.2(78) *Training for an authorized nuclear pharmacist.* Except as provided in 41.2(79), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

a. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements of 41.2(78)*"b"* and whose certification has been recognized by the NRC or agreement state; or

b. Has completed 700 hours in a structured education program consisting of both:

(1) Didactic training in the following areas:

1. Radiation physics and instrumentation;
2. Radiation protection;
3. Mathematics pertaining to the use and measurement of radioactivity;
4. Chemistry of by-product material for medical use; and
5. Radiation biology; and

(2) Supervised practical experience in a nuclear pharmacy involving:

1. Shipping, receiving, and performing related radiation surveys;
2. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;
3. Calculating, assaying, and safely preparing dosages for patients or human research subjects;
4. Using administrative controls to avoid medical events in the administration of by-product material; and
5. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

c. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual satisfactorily completed the requirements in 41.2(78)*"b"* and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

41.2(79) *Training for experienced nuclear pharmacists.* An individual identified as a nuclear pharmacist on an NRC or agreement state license or permit issued by an NRC or agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope before January 1, 2003, need not comply with the training requirements of 41.2(78).

41.2(80) *Training for nuclear medicine technologists.*

a. Nuclear medicine technologists shall meet the requirements of 641—42.4(136C).

b. The individual's permit to practice shall be posted in the immediate vicinity of the general work area and shall be visible to the public.

41.2(81) and **41.2(82)** Reserved.

41.2(83) *Provisions for the protection of human research subjects.*

a. A licensee may conduct research involving human research subjects only if the licensee uses the radioactive materials authorized on its specific license for the uses authorized on its license.

b. If the research is conducted, funded, supported, or regulated by another federal agency that has implemented Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

c. If the research will not be conducted, funded, supported, or regulated by another federal agency that has implemented the Federal Policy, the licensee shall, before conducting research, apply for and receive a specific amendment to its medical use license. The amendment request must include a written commitment that the licensee will, before conducting research:

(1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and

(2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subjects.

d. Nothing in this subrule relieves a licensee from complying with the other requirements of these rules.

41.2(84) *Calibration measurements of brachytherapy sources.*

a. Before the first medical use of a brachytherapy source on or after January 1, 2003, a licensee shall have:

(1) Determined the source output or activity using a dosimetry system that meets the requirements of 41.2(57);

(2) Determined the source positioning accuracy within applicators; and

(3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of 41.2(84)*"a."*

b. A licensee may use measurements that are provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine and that are made in accordance with 41.2(84)*"a"*(1) and (2).

c. A licensee shall mathematically correct the outputs or activities determined in 41.2(84)*"a"* for physical decay at intervals consistent with 1 percent physical decay.

d. A licensee shall retain a record of each calibration for three years after the last use of the source. The record must include:

(1) The date of the calibration;

(2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source;

(3) The source output or activity;

(4) The source positioning accuracy within the applicators; and

(5) The signature of the authorized medical physicist.

41.2(85) *Decay of strontium-90 sources for ophthalmic treatment.*

a. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 41.2(84).

b. A licensee shall retain a record of the activity of each strontium-90 source in accordance with 41.2(84).

41.2(86) *Therapy-related computer systems.* The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance must include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine sealed source positions from radiographic images; and

e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

41.2(87) *Written directives.* Each licensee or registrant shall meet the following objectives:

a. Prior to administration, a written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;

(4) For teletherapy, particle accelerator or X-ray: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy, including low-, medium-, and pulsed-dose-rate remote afterloaders:

1. Prior to implantation: treatment site, the radioisotope, number of sources, and source strengths; and

2. After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, equivalently, the total dose);

b. Prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

c. The final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

d. Each administration is in accordance with the written directive through checking both manual and computer-generated dose calculations and verifying that any computer-generated dose calculations are correctly transferred into the consoles of the medical units authorized by 641—Chapter 41;

e. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken;

f. If, because of the emergent nature of the patient's or human research subject's condition, a delay in order to provide a written directive jeopardizes the patient's or human research subject's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's or human research subject's record. A written directive must be prepared within 48 hours of the oral directive; and

g. A copy of the written directive in auditable form shall be retained for three years after the date of administration.

641—41.3(136C) Therapeutic use of radiation machines.

41.3(1) Scope and applicability.

a. This subrule establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines.

b. The use of therapeutic radiation machines shall be by, or under the supervision of, a physician who meets the training/experience criteria established by 41.3(5).

c. Unless specifically required otherwise by 641—41.3(136C), all registrants are subject to the requirements of 641—Chapters 38 to 40.

41.3(2) Definitions. In addition to the definitions provided in 641—38.2(136C) and 641—40.2(136C), the following definitions are specific to 641—41.3(136C).

"Accessible surface" means surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

"Added filtration" means any filtration which is in addition to the inherent filtration.

"Beam-limiting device" means a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

"Beam-scattering foil" means a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.